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| 09/381,561      | 09/17/99    | JACKSON              | J 2426-1-001        |

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EXAMINER

PHAM, M

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/381,561

Applicant(s)

JACKSON, JAMES RICHARD

Examiner

Minh-Quan K. Pham, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on March 20, 2001, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/381,561 is acceptable and a CPA has been established. An action on the CPA follows. Accordingly, the amendment filed February 6, 2001, has been entered as Paper No. 12.

### ***Claim Status***

Claims 20-39 are pending.

### ***Claim Objections***

Claim 38 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can only be in the alternative. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant amended the claims to specify that "said recording part only records said assay information without analyzation thereof in a form suitable for onward transmission for subsequent processing analysis at a remote data processing site."

This limitation contains new matter. Although applicant asserts that this amendment has support in the specification at least at page 13, second paragraph, the examiner has not found any support in the specification for a "recording part that only records said assay information without analyzation". On page 13, second paragraph, the specification states that "the results of the assay are not available to a user until further, remote, processing has occur." This passage does not indicate that the recording part does not perform analyzation, only that the result is not available to the user. Because the specification does not provide support for the claim amendment, the claims are rejected under 35 U.S.C. 112, first paragraph, as containing new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Previous rejection under 35 U.S.C. 112, second paragraph, are withdrawn in light of claim amendments presented in Paper No. 12.

#### NEW REJECTIONS

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 is vague and indefinite because it claims "[a] kit comprising an

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assessment device according to any preceding claim”; however, claim 38, a preceding claim, claims a method, not a device.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 20-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow (US 5,955,028).

Chow discloses a base unit to interface an assay substrate with a recording device, such as a computer, to control, record, and/or analyze the data from the microfluidic device (see column 5, line 25 to column 6, line 50). The assay substrate comprises a plurality of sample and reagent wells connected with microchannels (see column 11, line 48 to column 12, line 6; and Figure 1). Chow discloses an assay substrate (assay part) that is removable from a computer (recording part); therefore, Chow anticipates the invention as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. (US 4,756,884 and 4,963,498) in view of either Galen et al. (US 5,695,949) or Phillips et al. (US 5,179,005 and 5,426,032).

Hillman et al. disclose a capillary flow device for analysis comprising a capillary and sample wells where the sample passes along the capillary and reacts with one or more reagents (see Figures 1 and 3; column 3, lines 57-62; column 4, lines 1-4 and 14-19; and column 6, lines 28-31) to produce a detectable signal. The reagents may be supplied within the capillary by binding to the surface, whereby they may become dissolved in the fluid or may remain fixed to the surface (see column 6, lines 59-66). The device can have more than one capillary wherein each capillary may contain different reagents (see column 7, lines 32-47). Detection of the assay may be accomplished through the use of a detector such as a spectrophotometer, measurements of light scatter, etc. (see column 8, lines 6-59).

Hillman et al., however, differ from the claimed invention because they do not disclose an electronic recording device in data communication with the assay device.

Galen et al. disclose a detector for glucose concentration wherein the output of the detector is processed by a microprocessor which serve the following functions: calculate analyte level, output analyte level to the display, and store data (see column 13, lines 15-59; and Figures 3b and 4).

Phillips et al. disclose a detector (a spectrophotometer) for the detection of analytes wherein the detector comprises a microprocessor which serves the following functions: system timing, reading of the output from the spectrophotometer, program and data storage, calculation

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of analyte concentration, and outputting the analyte concentration data to the display (see column 8, lines 27-65; and Figures 2-4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the detector of Galen et al. or Phillips et al. in the device of Hillman et al. because the microprocessor has the well known advantage of large memory storage capacity and fast data processing.

### ***Response to Arguments***

Applicant's arguments filed February 6, 2001, have been fully considered but they are not persuasive.

Applicant presents a series of "steps which take a patient from obtaining a sample to providing a diagnosis" in order to argue the patentability of the instant claims. Applicant is reminded that the instant claims are drawn to an assessment device, not steps for diagnosis.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "providing raw data in the form of a detachable recording part to a remote data processing site for analysis") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Chow is silent on that "a recording part only records the assay information without analyzation thereof", this issue is addressed above under 35 U.S.C. 112, first paragraph.

Applicant argues that the combination of Hillman et al. in view of either Galen et al. or Phillips et al. “fails to disclose or suggest an assessment device having an assay part and a detachable recording part.” The examiner disagrees. The combination of references clearly shows an assay part (the capillary flow device) and a recording part (the detector and microprocessor). Further, one of ordinary skill in the art would have notice that the capillary device is detachable from the detector and microprocessor. Example 8 of Hillman et al. discloses an infrared LED analytical device (detector) “into which a capillary flow cartridge was to be inserted so that the output of its light would impinge upon the blood reservoir 1mm from the capillary entrance.” Clearly, this example shows a recording part (LED detector) that is detachable from an assay part (capillary device). Further, in column 17, lines 40-52, Hillman et al. disclose a photodetector, wherein “such apparatus may include a housing for receiving and holding the device ...” Clearly, by containing “a housing for receiving” the assay device the photodetector is inherently detachable from the assay device. Further, Figures 3 and 4 of Phillips et al. and Figure 4 of Galen et al. clearly show a recording part that is detachable from the assay device. Therefore, applicant’s argument that Hillman et al. in view of either Galen et al. or Phillips et al. “fails to disclose or suggest an assessment device having an assay part and a detachable recording part” is not persuasive.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.  
May 14, 2001



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05/19/01